

Applicant : Amanda S. Schilling et al.  
Serial No. : 10/090,798  
Filed : March 06, 2002  
Page : 2 of 8

Attorney Docket No.: Navy Case 83202

## RESPONSE AND REMARKS

### I. Status of the Claims

Claims 1, 4, 5, 7, 10-16, and 23 are pending in the application.

Claims 1, 4, 5, 7, 10-16, and 23 are rejected under 35 U.S.C. § 103 for obviousness.

Claim 1 is the sole independent claim.

### II. Response to the Office Action

Applicants appreciate the Examiner's explanation of the disposition of the claims, but respectfully request that the Examiner reconsider the rejection stated in the Office Action. Applicants respectfully submit that, in light of the nature of the art with which the invention is concerned, there has been an insufficient showing of a teaching, suggestion, or motivation to combine the cited references so as to establish that the claimed invention would have been obvious. Moreover, there is no showing that a person of ordinary skill in the art would have had a reasonable expectation of the success in the result of combining the teachings of the references.

The rejection under § 103 is based on Clouston (U.S. Patent No. 3,617,178)("Clouston") in view of Paidhungat *et al.* (*Journal of Bacteriology*, 2000, Vol. 182, pp. 2513-2519)("Paidhungat") and Baker *et al.* (U.S. Patent No. 6,506,803)("Baker"). The reasoning behind the rejection was set forth in Item 10 of a previous Office Action mailed March 05, 2004 (Paper No. 20040225). According to the explanation, Clouston teaches a method of germinating *Bacillus* or *Clostridium* spores and killing the germinated spores. According to the explanation and the Clouston patent, germination is accomplished through the application of hydrostatic pressure in a range of from 100 to 20,000 psi, with the simultaneous or subsequent application of heat or radiation. It is acknowledged that Clouston does not teach the use of dipicolinic acid (DPA) and calcium, and does not teach the use of a surfactant or enzymes. Paidhungat is cited for teaching a germinant containing "<20 mM to 90 mM calcium ions and dipicolinic acid" to germinate *Bacillus* spores. Baker is cited as teaching a method to germinate and inactivate

Applicant : Amanda S. Schilling et al.  
Serial No. : 10/090,798  
Filed : March 06, 2002  
Page : 3 of 8

Attorney Docket No.: Navy Case 83202

bacterial cells and spores by exposing them to an oil-in-water emulsion having water, a surfactant, an oil, an enzyme, and a buffer.

After summarizing the cited references, the Office Action provides the following reasoning for the rejection:

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Clouston's method and composition according to the teachings from Paidhungat et al. and Baker et al. . . . Paidhungat et al. remedy the deficiency of dipicolinic acid and calcium ions in Clouston's teachings, and Baker et al. remedy the deficiency of enzyme and surfactant in Clouston's method.

None of the above discussed prior art references teach the exact same concentration for water, dipicolinic acid or surfactant on weight basis of the total composition. However, the adjustment of particular conventional working conditions (e.g., the ratios of each one of [the] components in a composition, or their molar concentration etc.) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter, which is well within the purview of the skilled artisan.

Paper Number 20040225 at Item 10 (page 6). In addition to this, in an Office Action having a mailing date of March 03, 2005 (Paper No. 20050228) at Item 10, reference is made to Figure 4 at page 2517 of Paidhungat "which clearly teaches that a combination of 60 mM each of dipicolinic acid and  $\text{Ca}^{+2}$  gives maximum spore germination which would be the motivation for an artisan of ordinary skill to select a mixture of dipicolinic acid and calcium ions at a concentration of 60 mM for each ingredient from Baugh et al's teaching."

Applicants respectfully submit that the reasonings in these Office Actions do not establish a *prima facie* case of obviousness. The U.S. Circuit Court of Appeals for the Federal Circuit has often stated the burden and the standard regarding obviousness:

The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some *objective teaching in the prior art* or that *knowledge generally available* to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.

*In re Fine*, 837 F.2d 1071, 1074 (Fed.Cir. 1988)(emphasis added)(internal citations omitted). The Court has also stated, with respect to obviousness, that: "[A] proper analysis under § 103 requires, inter alia, consideration of two factors: 1) whether the prior art would

Applicant : Amanda S. Schilling et al.  
Serial No. : 10/090,798  
Filed : March 06, 2002  
Page : 4 of 8

Attorney Docket No.: Navy Case 83202

have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and 2) whether the prior art would have also revealed that in so making or carrying out, those of ordinary skill in the art would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493 (Fed.Cir. 1991), *cited in Noelle v. Lederman*, 355 F.3d 1343, 1348 (Fed.Cir. 2004).

The reasoning proffered in the cited Office Actions does not satisfy the requirements that the USPTO establish objective teachings leading a person of ordinary skill in the art to combine the cited references, nor does it satisfy the requirement that there be a reasonable expectation of success in the combination. These teachings must be found either in the prior art itself or in the knowledge generally available to one skilled in the art. The reasoning instead is that Clouston teaches a method using hydrostatic pressure to germinate spores and then simultaneously or subsequently killing the germinated spores. With this as a primary reference, the statements are made that Paidhungat "remed[ies] the deficiency" of DPA and calcium ions in Clouston, and Baker "remed[ies] the deficiency" of enzyme and surfactant in Clouston's method.

The reason this argument fails to establish a *prima facie* case of obviousness is that there is no showing of an objective teaching in the prior art or the general knowledge in the art at the time to suggest that Clouston had any deficiencies. Nothing is cited from the prior art or knowledge, nor can it be found, to suggest that Clouston's method is deficient in any way, much less in the specific ways "remedied" by Paidhungat. and/or Baker. In the absence of a teaching of a deficiency, which has not been shown in any Office Action, no reason is given for one of ordinary skill at the time, with knowledge of Clouston, to combine its teachings with either of the other two references and hence no *prima facie* case of obviousness has been made.

It is likewise not sufficient, in the absence of an objective teaching, to merely substitute one component or step in a reference for a component or step in another reference. *See, e.g., In re Fine, id.* at 1074-1075. Furthermore, simply adding a component or step, again without an objective teaching in the prior art or knowledge in the art, is to say that it would have been obvious to try the claimed invention. "[O]bvious to try" is not a legitimate test of patentability." *In re Geiger*, 815 F.2d 686, 688 (Fed.Cir. 1987).

In the prosecution of Applicants' application and in the absence of an objective teaching in the prior art, the only teaching that there is a "deficiency" in Clouston comes from the

Applicant : Amanda S. Schilling et al.  
Serial No. : 10/090,798  
Filed : March 06, 2002  
Page : 5 of 8

Attorney Docket No.: Navy Case 83202

application itself. No other objective reason in the prior art or knowledge at the time exists to suggest a deficiency of DPA/calcium or surfactants and enzymes. Using the claimed invention as a blueprint to discern deficiencies in the prior art, of course, is impermissible hindsight, *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed.Cir. 1983), and cannot support a *prima facie* case of obviousness.

While Applicants submit that the foregoing analysis is sufficient reason to withdraw the pending rejections, there are additional reasons why the cited references do not render the claimed invention obvious. As cited above, a finding of obviousness based on prior art also requires that there be a reasonable expectation that the combination would succeed. In this case, there is none. While it is true, as has been stated in the Office Actions, that Clouston can be seen as a teaching of a generalized method of simultaneous or subsequent germination and killing, it must also be recognized that Clouston teaches a particular way of doing this. Clouston *requires* the application of from 100 to 20,000 psi of hydrostatic pressure. This can be applied to a liquid or solid. Under these conditions of pressure, there is simply no basis upon which it can be argued that adding DPA and calcium would have any effect at all, much less a successful one. The same is true of the emulsion and other components taught by Baker. It has likewise not been shown that any of these components would operate as germinants under the conditions required by Clouston. Predictability must be shown when adding or substituting components, and the requirement for predictability is especially required in the chemical and biological arts. As the legal authorities cited above require, it is not sufficient, in the absence of the objective teaching, to simply substitute germination with DPA/calcium for germination with pressure, or to add additional components.

It is likewise true that there is no reasonable expectation of success in combining the DPA and calcium of Paidhungat with the emulsion of Baker. Emulsions by the very nature thereof require immiscibility of components. There is no objective teaching of a reasonable expectation of success that one could add the highly acidic DPA and the calcium cations to the emulsion without significantly altering the miscibility of the components and the claimed effect thereof on spores and germinated spores.

In addition to the foregoing, it is also evident that the cited references would not be combined by a person of ordinary skill because they teach away from each and away from the

Applicant : Amanda S. Schilling et al.  
Serial No. : 10/090,798  
Filed : March 06, 2002  
Page : 6 of 8

Attorney Docket No.: Navy Case 83202

claimed invention. Clouston, for example, requires the use of from 100 to 20,000 psi of hydrostatic pressure. Baker teaches an emulsion for use on surfaces and foodstuffs. See Baker at col. 1, ll. 15-28. One interested in decontaminating areas and foodstuffs would not look to the teachings of a method requiring the pressures taught by Clouston. It is not simply that the two methods cannot be combined (although in fact there is great doubt that the emulsion of Baker would survive the pressure of Clouston), but that one interested in decontaminating areas and foodstuffs simply would not look to a method that requires high pressures. In this respect, the two references are not analogous in that they require very different conditions for achieving the goals.

Paidhungat is cited for its teaching of the use of DPA and calcium ions as spore germinants. Paidhungat, however, very specifically teaches away from Applicants' claimed invention. Paidhungat's Figure 4 and the accompanying text (both at p. 2517) show and state the following: "Strikingly, the triggering of spore germination exhibited a sigmoidal response to  $[Ca^{2+} - DPA]$ ; at concentrations below 20mM,  $Ca^{2+} - DPA$  had little effect on the spore titers, followed by a logarithmic increase in spore titers with  $[Ca^{2+} - DPA]$ , and a plateau at  $Ca^{2+} - DPA$  concentrations beyond 60 mM (Fig. 4)." Figure 4 and the text indicate that spore germination actually decreased at  $Ca^{2+} - DPA$  concentrations above 60 mM. Whether Paidhungat's observations resulted from the basic solution used (incubation was in a pH 8.0 solution, see Paidhungat at 2517), from the heat activation, or some other factor is not known. What is known is that Paidhungat is a very strong and specific teaching away from Applicants' claimed invention of  $Ca^{2+} - DPA$  in a range of from about 10 mM to about 150 mM.

Finally, Applicants also respectfully submit that the statement in the March 05, 2005 Office Action (cited above) is incorrect. Without some teaching of predictability, one cannot say that selecting the proper amounts of each component and the correct concentrations and ratios of each requires only judicious selection and routine optimization. The very art cited by the USPTO here teaches otherwise. Paidhungat shows the "striking" observation that a relatively small change in concentration of the  $Ca^{2+} - DPA$  resulted in a very large change in the spore germination efficacy. This "striking" result did not come from judicious selection or routine optimization.

Applicant : Amanda S. Schilling et al.  
Serial No. : 10/090,798  
Filed : March 06, 2002  
Page : 7 of 8

Attorney Docket No.: Navy Case 83202

### Conclusion

Applicants respectfully submit that the USPTO has failed to establish a *prima facie* case of obviousness. There is no objective teaching that would lead one of skill in this art to selectively pick components from Paidhungat and/or Baker to combine with either the specific or general teaching of Clouston. There is no showing of any prior art or knowledge that would indicate "deficiencies" in Clouston, nor any showing of why one would select the specific components from Baker and Paidhungat to "remedy" those deficiencies. Moreover, even if the missing objective teaching were found, there is no showing that simply combining these selected components would lead to a reasonable expectation of success. As shown, the art itself teaches against such a reasonable expectation. The art itself also teaches that more than just judicious selection and routine optimization are required, at least in this art. Because it is impermissible to use an "obvious to try" standard, or to use Applicants' invention as a blueprint for selecting specific components, there is no showing that Applicants' invention would have been obvious at the time it was made.

Applicants submit that the claims are in compliance with the law, would not have been obvious, and are in condition for allowance. Early notice of allowability is respectfully solicited.

Should the Examiner have any questions about this application or Response or believe that discussion would advance the prosecution of this application, the Examiner is invited to contact Applicant's representative at the telephone number listed below.

Respectfully submitted,



OSCAR A. TOWLER, III  
Registration No. 33,803

Date: June 27, 2006

Applicant : Amanda S. Schilling et al.  
Serial No. : 10/090,798  
Filed : March 06, 2002  
Page : 8 of 8

Attorney Docket No.: Navy Case 83202

**DEPARTMENT OF THE NAVY**  
**Naval Surface Warfare Center – Dahlgren Division**  
**Office of Counsel – Code XDC1**  
**17320 Dahlgren Road**  
**Dahlgren, Virginia 22448-5100**  
**Telephone: (540) 653-4029**      **Customer No. 23501**

<p><b>DEPOSIT ACCOUNT USE</b> <b>AUTHORIZATION</b> Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 50-0967</p>
--